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<b>(21) International Application Number:</b> PCT/DK98/00436 <b>(22) International Filing Date:</b> 9 October 1998 (09.10.98) <b>(71) Applicant (for all designated States except US):</b> SANACARE APS [DK/DK]; Symbion, Fruebjergvej 3, D-2100 København Ø (DK). <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> ALSING-FREDERIKSEN, Nils [DK/DK]; Symbion, Fruebjergvej 3, DK-2100 København Ø (DK).	<b>(81) Designated States:</b> AL (Utility model), AM (Utility model), AT (Utility model), AU, AZ, BA, BB, BG (Utility model), BR (Utility model), BY (Utility model), CA, CH, CN (Utility model), CU, CZ (Utility model), DE (Utility model), DK (Utility model), EE (Utility model), ES (Utility model), FI (Utility model), GB, GE (Utility model), GH (Utility model), GM, HR, HU (Utility model), ID, IL, IS, JP (Utility model), KE (Utility model), KG (Utility model), KP, KR (Utility model), KZ (Utility model), LC, LK, LR, LS (Utility model), LT, LU, LV, MD (Utility model), MG, MK, MN, MW, MX (Utility model), NO, NZ, PL (Utility model), PT (Utility model), RO, RU (Utility model), SD, SE, SG, SI, SK (Utility model), SL, TJ (Utility model), TM, TR (Utility model), TT, UA (Utility model), UG, US; UZ (Utility model), VN (Utility model), YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>In English translation (filed in Danish).</i>	
<b>(54) Title:</b> DIET FOOD		
<b>(57) Abstract</b> <p>The present invention relates to a diet food for the control of a person's calorie intake. In particular the invention relates to a diet foot containing a combination of soluble fibre, simple carbohydrates and acid-stable proteins. The diet food is suitable for reducing a person's body mass and also acts to lower an elevated cholesterol leve. The object of the invention is to make available a diet food which can be used and taken daily and can replace one, more than one, or all the daily meals of a person who is obese or who belongs to one of the above-mentioned risk groups, i.e. persons who are on either a low calorie diet or an ultra-low calorie diet.</p>		

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## DIET FOOD

The present invention relates to a diet food for the control of a person's calorie intake. In particular the invention relates to a diet food containing a combination of soluble fibre, simple carbohydrates and acid-stable proteins.

5 The diet food is suitable for reducing a person's body mass and also acts to lower elevated cholesterol levels and brings about a general improvement in the digestion.

The application of diet foods for use in the control of a person's calorie intake is generally intended for the treatment of persons who are cosmetically obese and/or persons belonging to a risk group, e.g. Adipositas in conjunction with cardiovascular diseases (blood fibre diseases such as myocardial infarction and arteriosclerosis) or  
10 noninsulin-dependent diabetes. Obese persons are treated differently depending on the degree of obesity. Severe obesity (BMI [body mass index] exceeding  $27 \text{ kg/m}^2$ ) is normally treated under medical supervision using ultra-low calorie diets with diet foods having a nutrient content complying with the relevant EU regulations (cf. Commission

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15 Directive 96/8/EC). Cosmetically obese persons are normally treated with low-calorie diets wherein no special requirements are made on the diet foods. Traditionally, diet foods specifically for the treatment of severely obese persons are produced from *inter alia* milk constituents and therefore possess a characteristic milky taste.

It is therefore an object of the invention to make available a diet food which in  
20 conjunction with the change in eating habits necessitated by a diet is easy to take and moreover is pleasant-tasting and refreshing. Furthermore, it should be suitable to be used and taken daily and to replace one, more than one, or all the daily meals of a person who is obese or belongs to one of the above-mentioned risk groups, i.e. persons who are on either a low calorie diet or an ultra-low calorie diet. The diet food should thus result in a  
25 reduction in body mass, act to lower an elevated cholesterol level, and bring about a general improvement in the digestion.

The object is achieved by a diet food in accordance with the invention as described in Claim 1 and as described in the claims relating to use. Particularly advantageous embodiments of the invention are described in the other dependent claims.

5 On the basis of a combination of soluble dietary fibre, simple carbohydrates and acid-stable proteins, dissolved in power form in a fluid, e.g. water or fruit juice, a potable diet food is made available which satisfies in a pronounced degree the consumer's demand for a product that is easy to prepare and take and which is moreover pleasant-tasting. Even when taken by persons for whom it replaces all meals (ultra-low calorie diet under medical supervision), the refreshing juice-like taste of the diet food according to the  
10 invention encourages easier diet compliance compared with the milk-based diets known hitherto.

Above all, with the diet food according to the invention a product is made available that can be taken as a filling drink which can be taken by all persons including those suffering from e.g. milk allergy, i.e. persons having over-sensitivity to milk products in  
15 general. This is in contrast to traditional milk-based products, e.g. products based on skim milk powder, which are not acid-based.

In addition, the soluble dietary fibre increases the person's feeling of satiety as it passes through the body. This is brought about primarily by the soluble fibre forming a gel and swelling in the stomach, which acts to effectively fill the stomach and has a surprisingly  
20 satiating effect. Furthermore, in the small intestine, where the nutrients in ingested foods are absorbed, the fibre brings about a thickening of the intestinal contents. This has the effect of reducing or delaying the uptake of the nutrients in the small intestine and causes the feeling of satiety to persist for a relatively longer time than usual. Finally, the increased viscosity of the intestinal contents has the effect that the region of the intestine  
25 in which nutrient uptake takes place is displaced or moved further down in the small intestine. This shift of the presence of nutrients to the lower part of the small intestine

has the effect of causing the body to believe that the person has taken too much food or a sufficiency of food.

In summary, therefore, what happens is that the actual emptying of the stomach contents into the small intestine proceeds at a slower rate, causing the person to experience a greater feeling of fullness than at the normal rate of emptying. The lower part of the small intestine is called the ileum (the "twisted intestine"), and the phenomenon described above is therefore called the "intestinal brake".

The diet food acts in two further ways: the special combination of fibre, as mentioned above, promotes the formation of a gel in the small intestine, where it triggers the "intestinal brake" which gives rise to a persistent feeling of fullness. Further, the simple carbohydrates provide the body with energy and also act rapidly to induce a perception of fullness.

From the small intestine the intact soluble fibre passes into the large intestine where it is broken down (fermented) by the intestinal bacteria. In this way the fibre promotes the growth of bacterial strains having a beneficial effect on the organism, *inter alia* Bifido bacteria. At the same time the growth of pathogenic bacteria is inhibited. In summary, this results in the nutrients being broken down and taken up in a manner of optimal benefit to the person's health and wellbeing.

The carbohydrate content of the diet food provides the body with energy and has a satiating effect. Until recently the opinion or conviction was held that when a person's carbohydrate intake was in excess of the body's requirements, carbohydrates, particularly those based on sugars, were converted into fat and that in this way carbohydrates could lead to obesity. However, new research findings in the field have shown that this is not the case. In fact it has been found that contrary to expectation, an increased intake of sugars, derived e.g. from citrus fruits such as grapefruit, can actually result in weight loss. This can be explained by the following distinct mechanisms.

(1) The body's stores of carbohydrate are relatively small, their capacity being at most sufficient to supply the body's normal requirement of carbohydrate for approximately 12 hours. At the same time it may be mentioned that carbohydrates are particularly important e.g. in connection with the control of the blood sugar level and for the brain and nervous system. The body therefore gives a very high priority to maintaining these carbohydrate stores. One may say that a person will automatically continue his or her food intake until the point is reached where enough carbohydrate has been stored to supply the body's natural requirements. Thus it is the carbohydrate content of a diet food or of a total diet which decides and determines the total quantity of food that a person takes. It has been shown in numerous clinical trials that when the fat content was replaced with carbohydrates, subjects automatically lost weight even if they were allowed to eat as much carbohydrate-containing food as they were able or wanted to.

(2) An increased intake of carbohydrates increases the body's metabolic rate. Thus, easily metabolised simple carbohydrates, such as sugars from e.g. maltodextrin or grapefruit, will cause an increase in the body's metabolic rate.

(3) When the satiating effects of fat and carbohydrates are compared, it is found that the intake of one calorie/joule in the form of carbohydrates is more effective in creating a feeling of fullness than the intake of one calorie/joule in the form of fat. Thus a feeling of fullness can be achieved by the intake of fewer calories when consuming carbohydrates than when consuming fats.

Persons on a low-calorie diet (i.e. slimmers) are in a state of starvation and the body adapts to the lack or deprivation of protein and energy by a hormonal response and a metabolic change. Most of its energy requirements are supplied from stored fat.

During prolonged starvation proteins are lost from the skeletal muscle groups in order to maintain the bodily functions. The loss of muscle mass unnecessarily weakens the body. By supplying the body with suitable amounts of protein together with a minimum of calorie-rich food sources in the form of fat, by the use of a diet food according to the

invention, it is possible to maintain the body's protein balance and increase weight loss, primarily through the loss of fat.

Thus the invention's object is achieved of making available a diet food which can be used and taken daily and replace one, more than one, or all the daily meals of a person who is obese or belongs to one of the above-mentioned risk groups, i.e. persons on either a low calorie diet or an ultra-low calorie diet.

pH-stable, high biological value proteins formulated as a low-calorie non-alcoholic drink (preferably of a character resembling fruit-juice) may therefore be attractive as a general protein supplement in a slimming diet that includes juices. Another possible result of a protein supplement will generally occur in the form of a reduced appetite.

The protein source in the diet food according to the invention consists preferably of a pH-stable whey protein and/or soya protein of high biological value, high in essential amino acids and preferably free from lactose and animal fats in general.

#### Example of embodiment

The diet food according to the invention, in a preferred combination, consists of the following mixture of ingredients (all quantities expressed as percentages by weight):

- 10-80% proteins, especially 43-53%,
- 3-30% fat, especially 4-7%,
- 5-75% carbohydrate, especially 20-30%,
- 5-40% fibre, especially 8-13%,
- 0.05-2% vitamins, especially 0.3-0.7%,
- 2-12% minerals, especially 6-10%,
- 1-5% residue, especially 2-4%,

In a particularly preferred combination the proteins consist of:

- 10-70% whey protein, especially 43-53%

and/or

0-70% soya protein, especially 0-10%;

the fats of:

3-30% vegetable fat, especially 4-7% oil such as evening primrose oil and soya  
oil;

the carbohydrates of:

5-75% monosaccharides and disaccharides from maltodextrin (glucose, dextrose)  
and citrus fruits, especially 20-30%;

the fibre of:

5-40% oligosaccharides and polysaccharides, especially 8-13% in the form of  
inulin;

the vitamins of:

0.05-2%, especially 0.3-0.7% of a mixture of vitamins A, C, E, D, B1, B2, B6,  
B12, folic acid, niacin, pantothenic acid and biotin;

the minerals of:

2-12%, especially 6-10% of a mixture of iron, zinc, copper, manganese, selenium,  
iodine, calcium, phosphorus, potassium, sodium and magnesium;

and the ancillary substances of:

0-2%, especially 0.2-0.6% in the form of tricalcium phosphate.



## CLAIMS FOR WORKING MODEL

1. A diet food designed for reducing body mass and lowering an elevated cholesterol level in a person, which is new in that it comprises a combination of soluble dietary fibre, simple carbohydrates (maltodextrin), acid-stable proteins, fat, and a residue comprising vitamins, minerals and ancillary substances.
2. A diet food according to Claim 1 wherein said simple carbohydrates preferably consist of sugars from maltodextrin (glucose, dextrose) and/or citrus fruits, particularly grapefruit.
3. A diet food according to Claim 1 wherein the acid-stable proteins preferably consist of low pH-stable high biological value proteins, derived in particular from whey proteins and/or soya proteins.
4. A diet food according to any of Claims 1-3 wherein said combination consists of the following mixture of ingredients (all quantities expressed as percentages by weight):

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  - 10-70% proteins, especially 43-53%,
  - 3-30% fat, especially 4-7%,
  - 5-75% carbohydrate, especially 20-30%,
  - 5-40% fibre, especially 8-13%,
  - 0.05-2% vitamins, especially 0.3-0.7%,
  - 2-12% minerals, especially 6-10%,
  - 0-2% residue, especially 0.2-0.6%,
5. A diet food according to Claim 4 wherein the combination comprises proteins in the form of 0-70% whey protein, especially 43-53%, and/or 0-70% soya protein, especially 0-10%, fats in the form of 3-30% vegetable fat, especially 4-7% oil such as evening primrose oil and/or soya oil, carbohydrates in the form of 5-75% monosaccharides and disaccharides, especially 20-30% in the form of sugars from

maltodextrin (glucose, dextrose) and/or citrus fruits, fibre in the form of 5–40% oligosaccharides and polysaccharides, especially 8–13% in the form of inulin, vitamins in the form of 0.05–2%, especially 0.3–0.7% of a mixture of vitamins A, C, E, D, B1, B2, B6, B12, folic acid, niacin, pantothenic acid and biotin, minerals in the form of 2–12%, especially 6–10% of a mixture of iron, zinc, copper, manganese, selenium, iodine, calcium, phosphorus, potassium, sodium and magnesium, and ancillary substances in the form of 0–2%, especially 0.2–0.6% of a mixture of tricalcium phosphate.

6. A diet food suitable for reducing body mass and lowering an elevated cholesterol level in a person, which is new in comprising a combination of soluble dietary fibre, simple carbohydrates and acid-stable protein and is free from lactose and animal fat.
7. A diet food according to any of the foregoing claims, wherein the combination of the individual constituents is dissolved in powder form in fluid, preferably water or fruit-juice, the latter being in particular grapefruit juice, orange juice or apple juice.
8. A diet food according to any of Claims 1–7 and otherwise as disclosed in the description.
9. The use of a diet food according to any of the foregoing claims 1–8 in conjunction with a low-calorie diet.
10. The use of a diet food according to any of the foregoing claims 1–9 in conjunction with an ultra-low calorie diet according to the relevant EU standard.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 98/00436

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A23L 1/29, A23L 1/30, A23L 1/305, A23L 1/307, A23L 1/308  
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## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CAPLUS, WPI, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0898900 A2 (SOCIETE DES PRODUITS NESTLE S.A.), 3 March 1999 (03.03.99)	1-10
X	DE 2844861 A1 (PHARMA HAMELN KERSTEIN GMBH KG), 30 April 1980 (30.04.80)	1-4,6-10
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## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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